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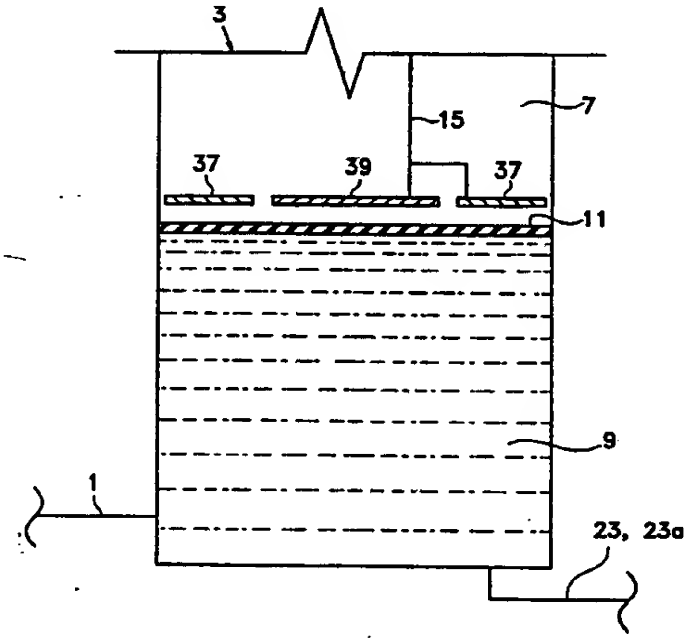

(57) Abstract

A fluid flow and pressure control system (10) having an accumulator (3) with a first chamber (7) and a second chamber (9) separated by a flexible membrane (11), a diaphragm or venturi pump (29) in fluid communication with the first chamber (7), a peristaltic pump or valve (21) in fluid communication with the second chamber (9), a volume sensor (13) communicating with the accumulator (3) for sensing volume changes in the second chamber (9), a surgical tool (5) in fluid communication with the second chamber (9) and a computer (17) for controlling the operation of the diaphragm or venturi pump (29) and the peristaltic pump (21) in response to a signal generated by the volume sensor (13).

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FLUID FLOW AND PRESSURE CONTROL SYSTEM

Backgr und of the Invention

The present invention relates to microsurgical equipment and, in particular, to ultrasonic microsurgical handpieces, irrigation/aspiration handpieces and control systems.

A typical (anterior chamber) ultrasonic surgical device consists of an ultrasonically driven handpiece with attached cutting tip and irrigating sleeve and an electronic control console. The handpiece assembly or probe is attached to the control console by an electric cable and flexible tubings. Through the electric cable, the console varies the power level transmitted by the handpiece to the attached cutting tip and the flexible tubings supply irrigation fluid to and draw aspiration fluid from the eye through the handpiece assembly.

A typical posterior segment surgical tool consists of a handpiece having a long, hollow outer needle or probe with a cutting port and a reciprocating or rotating hollow inner cutting needle. As the inner cutting needle cuts tissue through the cutting port, the severed tissue is aspirated into the inner needle through the cutting port and out of the handpiece by a flexible tube connected to a source of reduced pressure at the surgical tool control console. Material aspirated from the surgical site is replaced by an infusion fluid, such as saline solution, generally dispensed within the surgical site by a second, hollow infusion needle or probe. Posterior segment surgical tools are more fully described in U.S. Patents Nos. 3,996,935, 4,200,106, 4,696,298, 4,850,354 and 4,867,155, the entire contents of which are incorporated herein by reference.

The multiple connections for power, aspiration and irrigation between the handpiece and the console in such microsurgical instruments have made complex the preparation and interconnection of the equipment preparatory to the surgical procedure, with consequent concerns about maintaining sterility and assuring error-free connection. Accordingly, in modern versions of typical microsurgical instruments, the fluid handling connections have come to be centralized in a "cassette" which contains in one unit connections for the aspiration and irrigation lines, internal conduits for directing the flow of fluids and a collection container for aspirated fluid and tissue. The cassette typically is supplied in a

sterile package with the connecting tubing already attached. Thus, setting up the equipment requires only connecting the cassette tubing to the surgical handpiece and inserting the cassette into a receptacle on the console. The receptacle contains a device or devices to exercise control over the flow of fluids through the fluid conduits within the cassette. The cassette usually is discarded after a single use but also may be reusable if made from autoclavable materials.

Ophthalmic surgeons generally prefer to use the type of vacuum pump on which they were trained. Many cataract surgeons are trained on peristaltic pumps and, accordingly, they tend to prefer these pumps. On the other hand, a significant number of posterior segment surgeons are trained on venturi or diaphragm pumps and, of course, such systems tend to be preferred. However, pump preferences are based not only on these training factors, but equally significantly to pump selection are the different performance characteristics for each type of pump. For example, when performing anterior segment surgery (e.g. cataract surgery), most surgeons prefer the constant flow characteristics of a peristaltic pump that help to prevent chamber collapse upon the break-up of any occluding tissue. On the other hand, during posterior segment surgery (e.g. vitrectomy surgery), surgeons prefer the constant pressure of a diaphragm or venturi pumping system.

The prior art has, in general, provided separate pump control consoles for each of the different types of pumps, increasing the amount of acquisition, operating and maintenance expenses that must be paid by the surgeon. One approach for obviating the necessity of purchasing different systems for anterior and posterior segment surgery is disclosed generally in U.S. Patent No. 4,428,748. Specifically, a dual mode handpiece is disclosed that can be used for performing phacoemulsification and for performing posterior segment operations, such as in vitrectomy. Nonetheless, the versatile handpiece is limited by the control console that contains only a peristaltic pump and does not contain any means for providing a constant pressure at the handpiece.

Another device disclosed in U.S. Patent No. 3,496,878 to Hargest, et al, includes a peristaltic pump and a sensor that monitors the flow of fluid into a chamber to trigger operation of the pump. However, this system does not contain a fluid flow controller and does not have the capability of alternatively providing constant flow or constant pressure.

U.S. Patent No. 4,385,630 to Gilcher, et al., discloses a blood donation unit that includes a peristaltic pump and a pressure bag that monitors blood flow and actuates the pump. This system likewise does not have the capability of alternatively providing constant flow or constant pressure.

The system disclosed in U.S. Patent No. 4,604,089 to Santangelo, et al., includes a pressure accumulator that allows the surgeon to vary the pressure level within the irrigation system between one of two preselected pressures by opening and closing two push button valves. This system does not contain any means for alternately providing constant fluid flow or constant fluid pressure.

Accordingly, a need continues to exist for a surgical fluid flow control system capable of providing either constant fluid flow or constant fluid pressure.

Brief Description of the Invention

The present invention improves upon prior art fluid flow control systems by providing a system having an accumulator in fluid communication with a surgical handpiece and a volume sensor responsive to changes in fluid volume within the accumulator. Sensed volume changes are transmitted to a pressure controller and a flow controller through a microcomputer that adjusts the controllers to provide either a desired flow rate or a desired pressure level at the surgical handpiece.

Accordingly, one objective of the system of the present invention is to provide an improved fluid flow control system for use in surgical procedures requiring irrigation or aspiration.

Another objective of the system of the present invention is to provide an improved fluid flow control system capable of maintaining either a constant fluid flow rate or a constant fluid pressure at a remote surgical handpiece.

Another objective of the system of the present invention is to provide an improved fluid flow control system using variable capacitance for volume measurement.

Another objective of the system of the present invention is to provide an improved fluid flow control system using variable capacitance for fluid flow and pressure level management in the system.

Another objective of the system of the present invention is to provide an improved fluid flow control system using both a peristaltic pump and a venturi or diaphragm pump.

These and other and further objectives and advantage of the present invention will become apparent from the detailed description, claims and drawings that follow.

Brief Description of the Drawings

FIG. 1 is a schematic illustration of a first embodiment of the fluid flow and pressure control system of the present invention for use in surgical procedures requiring aspiration.

FIG. 2 is a schematic illustration of a second embodiment of the fluid flow and pressure control system of the present invention for use in surgical procedures requiring irrigation.

FIG. 3 is a plan view of the fluid accumulator used in the system of the present invention.

FIG. 4 is a cross-sectional view of the fluid accumulator used in the system of the present invention taken at line 4-4 in FIG. 3.

FIG. 5 is a schematic illustration of a third embodiment of the fluid flow and pressure control system of the present invention.

FIG. 6 is an enlarged, fragmentary, cross-sectional view of the accumulator/sensor of the present invention taken at circle 6 in FIG. 5.

Detailed Description of the Invention

As can be seen in FIGS. 1, 2 and 5, fluid flow and pressure control system 10 of the present invention generally contains fluid accumulator 3, pressure controller 29, fluid flow controller 21, volume sensor 13 and computer 17. Pressure controller 29 may be any suitable vacuum-type pump such as a diaphragm or venturi pump. Computer 17 preferable is an embedded controller such as the INTEL® model 80196. Accumulator 3 generally is located within cassette portion 45 of system 10 and contains first chamber or portion 7 and second chamber or portion 9. As can be seen in FIGS. 5 and 6, accumulator 3 may be placed near outside wall 47 of cassette portion 45 so as to be proximate sensor 13, which is contained within console portion 49 of system 10. First chamber 7 and second chamber 9 may be

separated by fixed, resilient membrane 11. Alternatively, accumulator 3 may be divided into first chamber 7 and second chamber 9 by filling accumulat r 3 with two immiscible fluids, such as a liquid and a gas. First chamber 7 communicates with pressure controller 29 through conduit 31 and second chamber 9 communicates with fluid flow controller 21 through conduit 23 and with tool or handpiece 5 through flexible conduit 1. If used, membrane 11 is preferably made from silicone rubber or other suitably compliant elastic material.

As can be seen in FIGS. 3, 4 and 6, volume sensor 13 may consist of a pair of concentric electrode plates 37 and 39 either proximate to (FIG. 6) or contained within (FIG. 4) first chamber 7 of accumulator 3 and connected to an oscillator circuit (not shown) in the console through cable 15. Alternatively, as can be seen in FIG. 6, electrode plates 37 and 39 may be located directly on circuit board 69. Electrode plate 37 and the liquid in second chamber 9 opposite electrode plate 37 form two plates of a capacitor. Likewise, electrode plate 39 and the liquid in second chamber 9 opposite electrode plate 39 form two plates of a second capacitor. These two capacitors are connected in series by a conductive path through the bulk of the liquid in second chamber 9 if accumulator 3 is filled with two immiscible fluids or through membrane 11 if membrane 11 is used and made from a conductive material. Connecting the two capacitors in series is equivalent to a single large capacitor with electrode plates 37 and 39 as its terminals. The effective value of the single large capacitor depends upon the thickness of the dielectric material (i.e. the gaseous gap between the interface between the two immiscible fluids and electrode plates 37 and 39 or the air gap between membrane 11 and electrode plates 37 and 39). Therefore, as the volume of liquid changes within second chamber 9, thereby causing the gas or air gap to shrink or enlarge, either by a change in position of the fluid interface or by membrane 11 either stretching into first chamber 7 or pulling into second chamber 9, the capacitance of the system will vary. When connected to an oscillator circuit whose frequency of oscillation varies depending upon the capacitance of the system, volume sensor 13 can detect minute volume changes in the liquid in second chamber 9 and communicates this information to computer 17 through cable 19. While volume sensor 13 as described above is preferred, other volume sensors 13, such as electrode or probe systems, photoelectric-cell systems, floats systems or thermo-hydraulic systems may also be used.

As can be seen in FIG. 1, when system 10 is used to control aspiration fluid flow and pressure, system 10 further includes aspiration fluid collection container 27 that communicates with fluid flow controller 21 through conduit 24. Container 27 may be integrally formed in cassette chamber 45 of system 10 or may be a separate container. Fluid flow controller 21 may be any suitable pump but a peristaltic pump is preferred. As can be seen in FIG. 2, when system 10 is used to control irrigation fluid flow and pressure, system 10 further includes an irrigation fluid source 25 that is connected to fluid flow controller 21a through conduit 55 and flow sensor 57. Fluid flow controller 21a may be a peristaltic pump or, if fluid source 25 is pressurized, fluid flow controller 21a may be a variable orifice valve or a valve having a variable on/off cycle. Flow sensor 57 through cable 59, provides computer 17 with the fluid flow data necessary to calculate the fluid flow rate through conduit 1 and permits computer 17 to calculate the pressure drop across conduit 1. Flow sensor 57 can be any sensor suitable for measuring fluid flow in a closed conduit and can be contained within the console of system 10 or be part of fluid source 25 and conduit 55 (i.e., a drop counter). If a peristaltic pump is used as fluid flow controller 21a in an irrigation fluid flow system, the flow rate through the system can be determined from the pump speed and flow sensor 57 may be omitted.

Referring to FIG. 1, when system 10 is used to control aspiration fluid flow and pressure, the surgeon selects either a target pressure or a target fluid flow rate in computer 17. Second chamber 9 is filled with fluid and system 10 is zeroed. If the surgeon has selected a target fluid flow rate, computer 17 activates fluid flow controller 21 through cable 35 and fluid flow controller 21 begins to draw fluid from second chamber 9 through conduit 23 and discharges the fluid into container 27 through conduit 24. Computer 17 adjusts the speed of fluid flow controller 21 to achieve the approximate desired flow rate. However, if the flow of fluid from the surgical site through handpiece 5 and conduit 1 is too low, fluid flow controller 21 will begin to draw down the volume of fluid in second chamber 9. This volume change is detected by volume sensor 13 and is communicated to computer 17. In response to this reduced volume in second chamber 9, computer 17, through cable 33, directs pressure controller 29 to reduce the absolute pressure in first chamber 7. This reduced pressure in first chamber 7 is communicated to second chamber 9, reducing the pressure

in second chamber 9 and causing increased fluid flow at the operative site through handpiece 5 and conduit 1 and into second chamber 9. On the other hand, if the fluid flow rate through handpiece 5 and conduit 1 is too high, computer 17 directs pressure controller 29 to increase the pressure in accumulator 3, thereby reducing the flow rate at the operative site through handpiece 5 and conduit 1 and into second chamber 9. The flow rate through handpiece 5 and conduit 1 is controlled by pressure controller 29 varying the pressure within accumulator 3, and fluid flow controller 21 operates at essentially a constant speed.

If the surgeon has selected a target pressure level, second chamber 9 is filled with fluid and system 10 is zeroed. Computer 17 activates pressure controller 29 to reduce the absolute pressure in first chamber 7 to approximately the target pressure and this reduced pressure level is communicated to second chamber 9, thereby causing fluid to flow into second chamber 9. In response to this increased fluid volume in second chamber 9, computer 17, through cable 35, activates fluid flow controller 21. If the amount of fluid drawn from second chamber 9 by fluid flow controller 21 is too great, the volume of fluid in second chamber 9 will decrease, and this volume decrease will be detected by sensor 13 and transmitted to computer 17. Computer 17 will reduce the speed of fluid flow controller 21 so that the volume of fluid in second chamber 9 remains constant. On the other hand, if the amount of fluid drawn from second chamber 9 by fluid flow controller 21 is too small, the volume of fluid in second chamber 9 will increase, and this volume increase will be detected by sensor 13 and transmitted to computer 17. Computer 17 will increase the speed of fluid flow controller 21 so that the volume of fluid in second chamber 9 remains constant. Pressure controller 29 maintains an essentially constant pressure within accumulator 3 while fluid flow controller 21 is the transfer mechanism used to maintain a constant volume in accumulator 3.

As can be seen in FIG. 2, if system 10 is used to regulate irrigation fluid flow and pressure, the operation of system 10 is essentially the same as described above. However, if a target pressure is desired and fluid flow controller 21a is a valve instead of a peristaltic pump, the liquid level in accumulator 3 is adjusted by opening and closing fluid flow controller 21a or variably throttling fluid flow controller 21a so as to maintain a constant volume of liquid in accumulator 3.

In addition to constant flow and constant pressure modes of

operation, system 10 can be adapted to hybrid modes of operation combining aspects of both. For example, the surgeon might select, in addition to a target flow rate, a minimum absolute pressure level (maximum vacuum level). System 10 will respond in a constant flow mode as long as the pressure level within the system did not reach the minimum level but respond in a constant pressure mode once the minimum pressure level was reached. Alternatively, the surgeon can select a target pressure and a maximum flow rate level. System 10 will respond in a constant pressure mode as long as the flow rate does not exceed the maximum level but respond in a constant flow rate mode once the maximum flow level is reached.

This description is given for purposes of illustration and explanation. It will be apparent to those skilled in the relevant art that change and modification can be made to the invention as described above without departing from its scope and spirit.

I claim:

1. A fluid flow and pressure control system, comprising:

a. an accumulator having a first chamber and a second chamber;

b. a pressure controller in fluid communication with the first chamber;

c. a fluid flow controller in fluid communication with the second chamber;

d. a volume sensor communicating with the accumulator for sensing volume changes in the second chamber;

e. a surgical tool in fluid communication with the second chamber; and

f. a means for controlling the operation of the fluid flow controller and the pressure controller in response to a signal generated by the volume sensor.

2. The system of claim 1 wherein the first chamber in separated from the second chamber by a flexible membrane.

3. The system of claim 1 wherein the first chamber is comprised of a gas filled portion of the accumulator and the second chamber comprises a liquid filled portion of the accumulator.

4. The system of claim 1 wherein the pressure controller is a diaphragm pump.

5. The system of claim 1 wherein the pressure controller is a venturi pump.

6. The system of claim 1 wherein the fluid flow controller is a peristaltic pump.

7. The system of claim 1 wherein the fluid flow controller is a variable orifice valve.

8. The system of claim 1 wherein the fluid flow controller is a valve having a variable on/off cycle.

9. The system of claim 1 wherein the volume sensor is a pair of concentric electrode plates located proximate to the accumulator.

10. The system of claim 1 wherein the means for controlling the operation of the fluid flow controller and the pressure controller in response to a signal generated by the volume sensor is a computer.

11. The system of claim 1 further comprising a source of irrigation fluid.

12. A fluid flow and pressure control system, comprising:

a. an accumulator having a first chamber and a second chamber separated by a flexible membrane;

b. a diaphragm pump in fluid communication with the first chamber;

c. a peristaltic pump in fluid communication with the second chamber;

d. a volume sensor proximate to and communicating with the accumulator for sensing volume changes in the second chamber;

e. a surgical tool in fluid communication with the second chamber; and

f. a computer for controlling the operation of the diaphragm pump and the peristaltic pump in response to a signal generated by the volume sensor.

13. The system of claim 12 wherein the volume sensor is a pair of concentric electrode plates located proximate to the first chamber.

14. The system of claim 12 further comprising a source of irrigation fluid.

15. A fluid flow and pressure control system, comprising:

a. an accumulator having a first chamber and a second chamber separated by a flexible membrane;

b. a venturi pump in fluid communication with the first chamber;

c. a peristaltic pump in fluid communication with the second chamber;

d. a volume sensor proximate to and communicating with the

accumulator for sensing volume changes in the second chamber;

e. a surgical tool in fluid communication with the second chamber; and

f. a computer for controlling the operation of the venturi pump and the peristaltic pump in response to a signal generated by the volume sensor.

16. The system of claim 15 wherein the volume sensor is a pair of concentric electrode plates located proximate to the first chamber.

17. The system of claim 15 further comprising a source of irrigation fluid.

18. A surgical fluid flow and pressure control system having a console and a cassette, comprising:

a. an accumulator having a first chamber and a second chamber separated by a flexible membrane located in the cassette;

b. a pressure controller in fluid communication with the first chamber located in the console;

c. a fluid flow controller in fluid communication with the second chamber located in the console;

d. a volume sensor located in the console proximate to and communicating with the accumulator for sensing volume changes in the second chamber;

e. a surgical tool in fluid communication with the second chamber; and

f. a computer located in the console for controlling the operation of the pressure controller and the fluid flow controller in response to a signal generated by the volume sensor.

19. The system of claim 18 wherein the pressure controller is a diaphragm pump.

20. The system of claim 18 wherein the pressure controller is a venturi pump.

21. The system of claim 18 wherein the fluid flow controller is a peristaltic pump.

22. The system of claim 18 wherein the fluid flow controller is a variable orifice valve.

23. The system of claim 18 wherein the fluid flow controller is a valve having a variable on/off cycle.

24. The system of claim 18 wherein the volume sensor is a pair of concentric electrode plates.

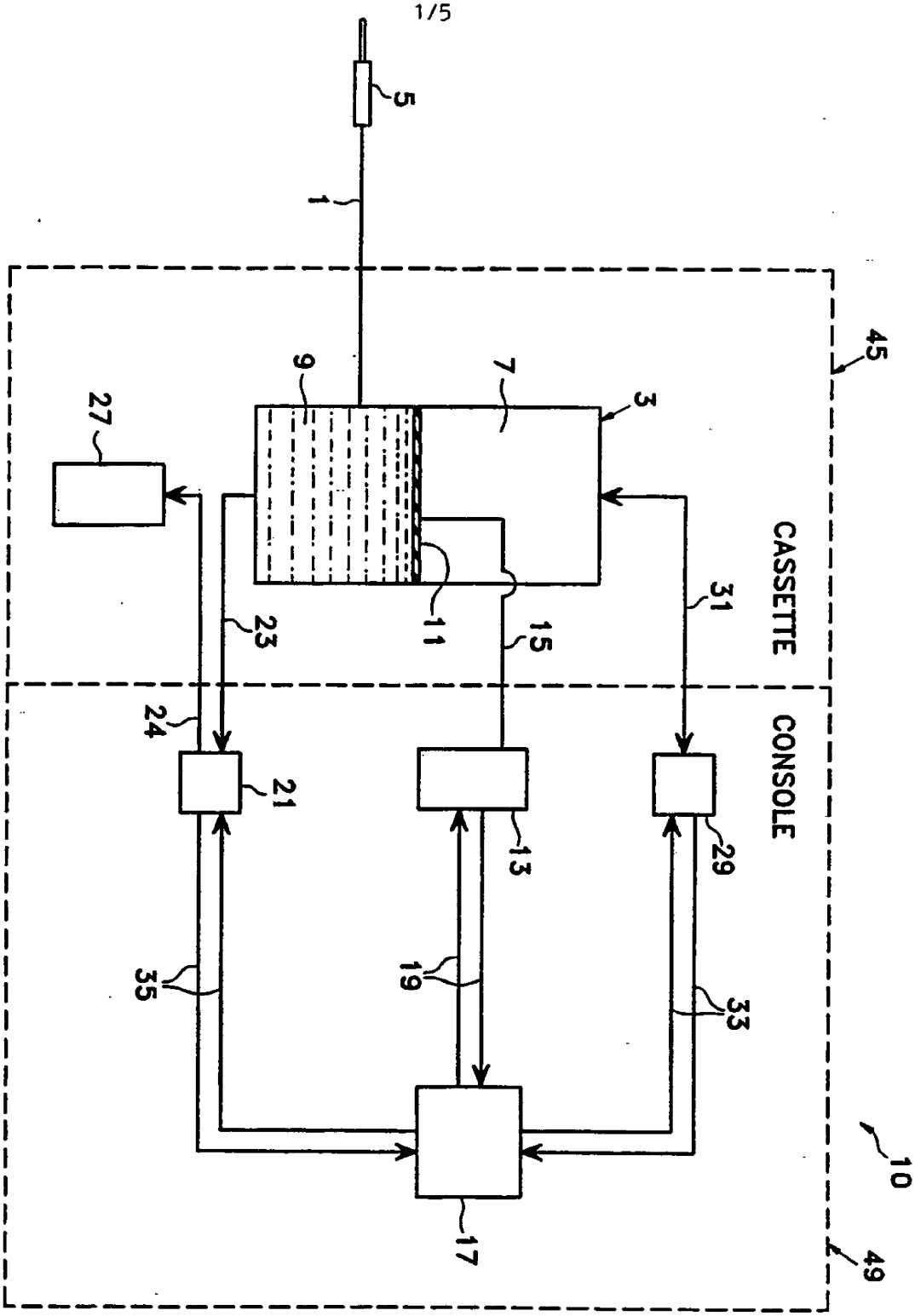
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FIG. 1

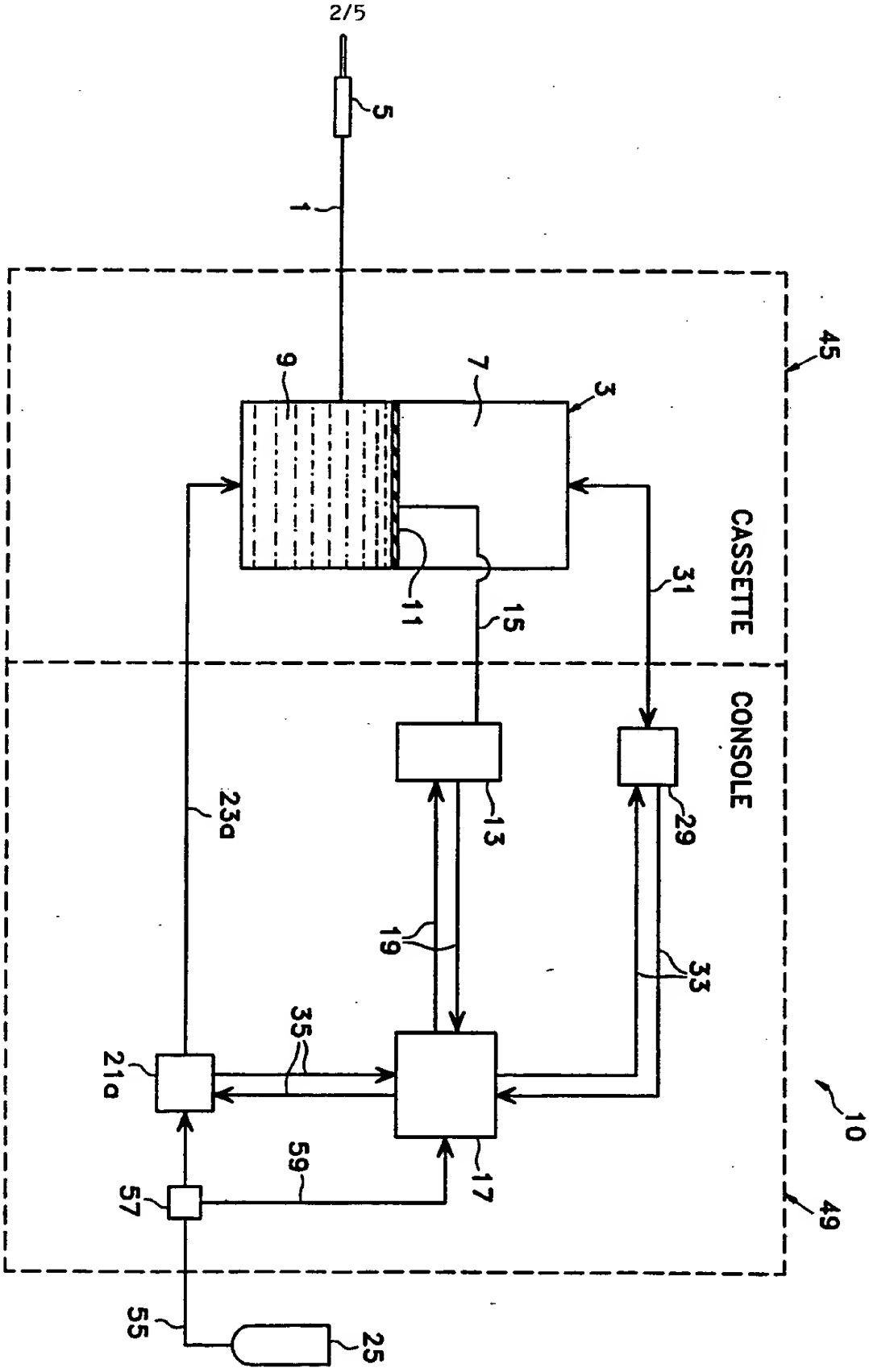
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FIG. 2

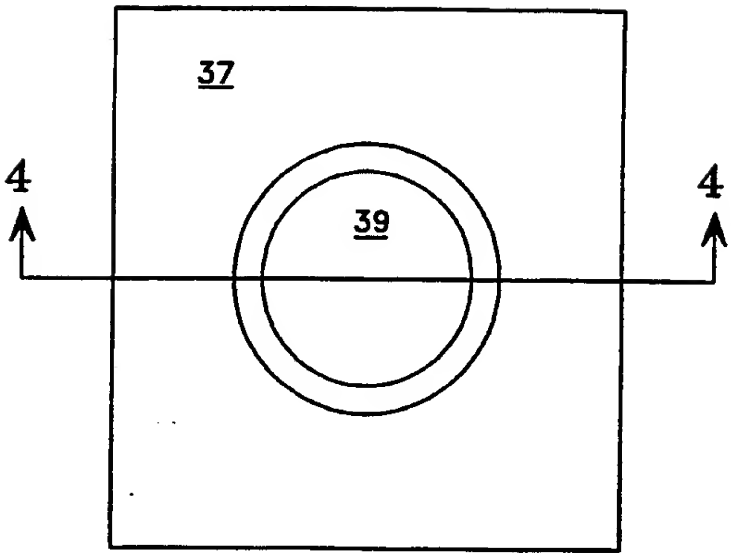

FIG. 3

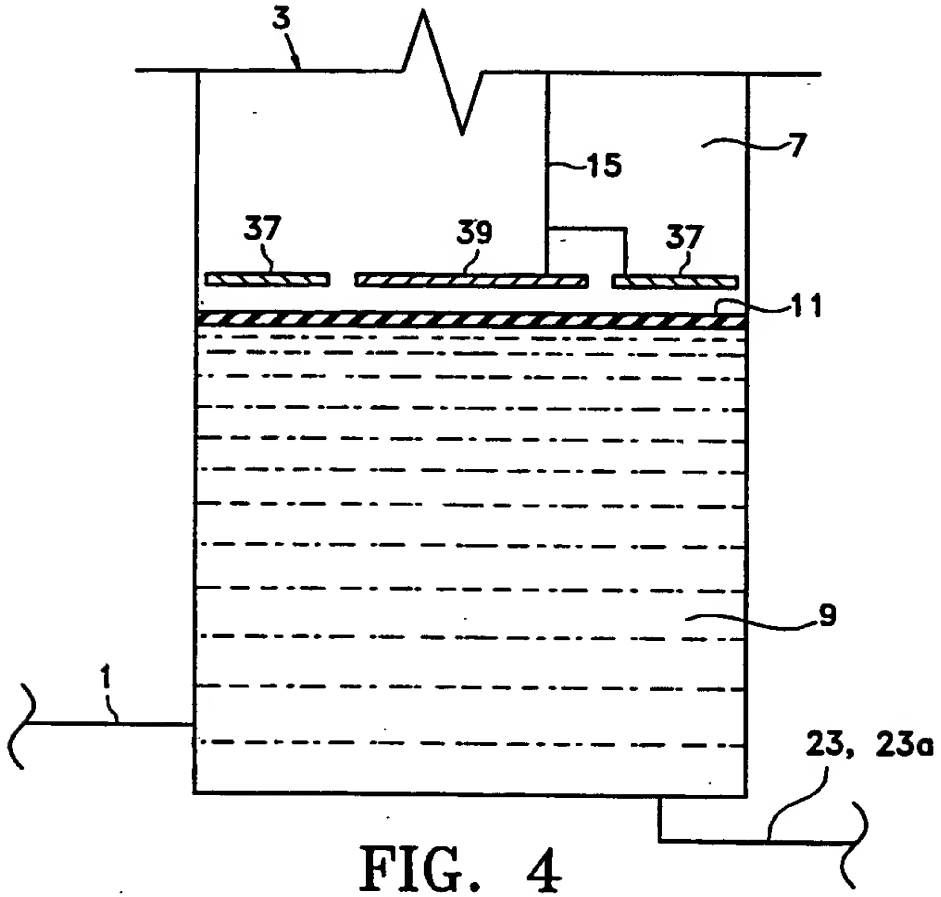

FIG. 4

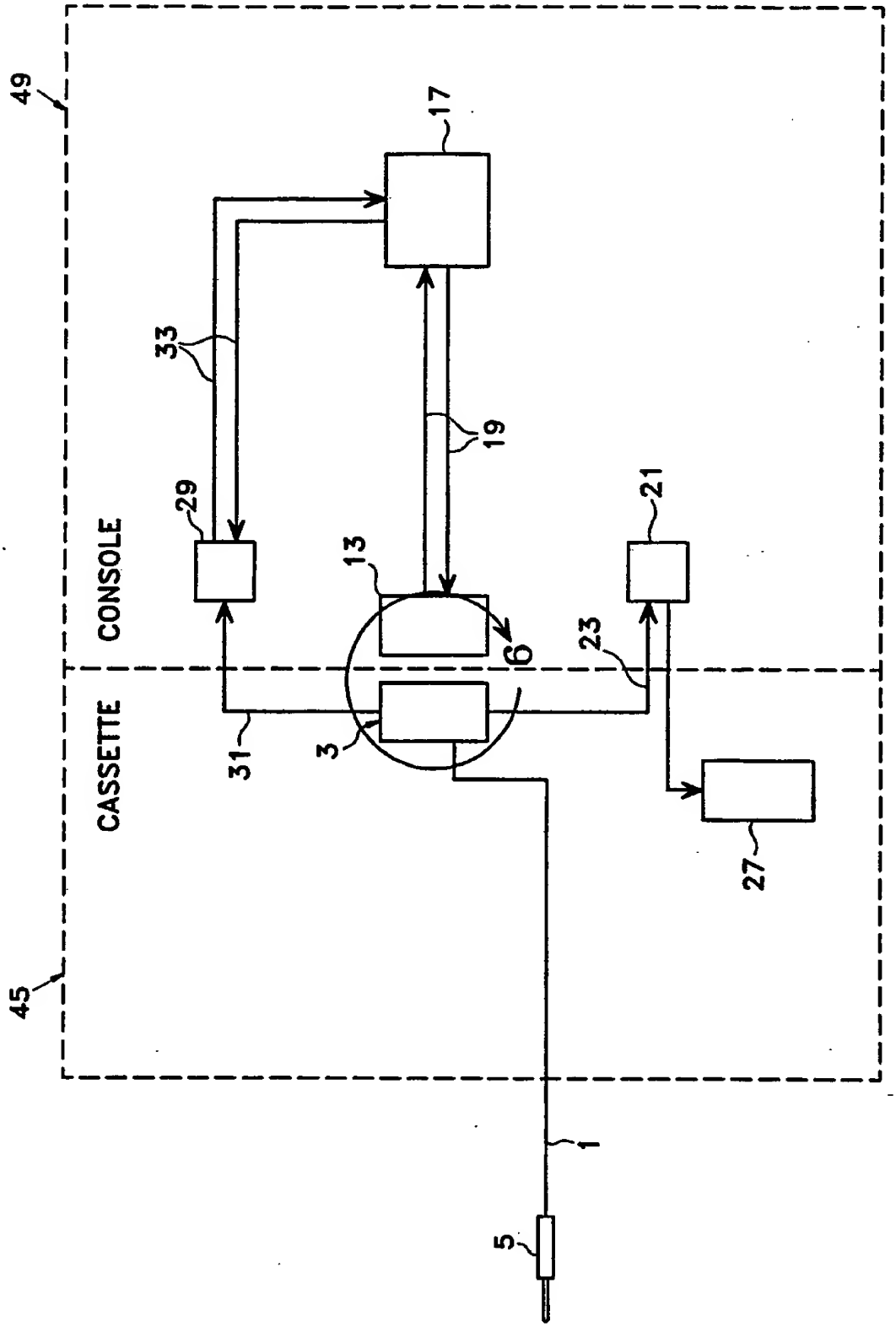

FIG. 5

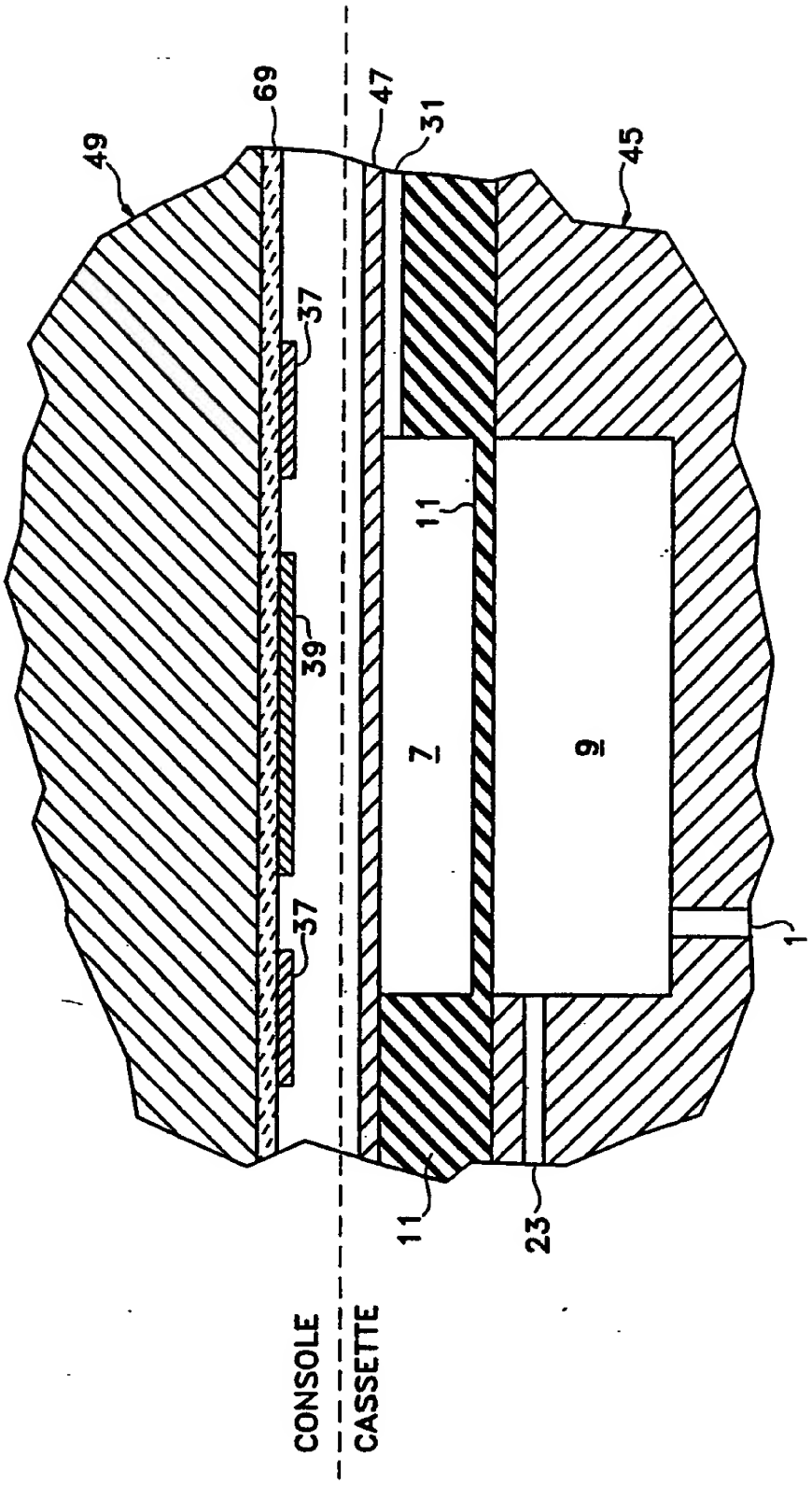

FIG. 6

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 93/01261

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61M1/00; A61F9/00

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61M ; A61F

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
07 JULY 1993	13.07.93
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	BARTON S.

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

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ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

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This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on
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